

**REMARKS**

Claims 1-17 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,077,527. The examiner urges that both the '527 and the subject application claim an adhesive comprising alkyl acrylate monomer and/or alkyl methacrylate monomer and nitrogen containing monomer. The examiner characterizes the '527 patent as not disclosing the presence of reactive sites in the polymer after polymerization and the claim language of the subject application claim as permitting the presence of the crosslinker claimed in the '527 patent.

Applicants submit that the claimed invention is patentable over the '527 patent.

The '527 patent does not disclose an adhesive composition that lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker as required in the practice of the claimed invention. While use of a composition comprising (iv) an acrylic monomer containing at least one group having a reactive hydrogen and (v) a crosslinker is disclosed in the '527 as being optional (see, e.g., col. 3, lines 21-27) it would be clear to one of ordinary skill in the art, from a fair reading of the '527 disclosure that the described composition must contain a compound comprising a reactive hydrogen and must contain a crosslinking agent. The disclosure of the '527 patent is concerned with problems associated with use of penetration enhancers in adhesives used in transdermal systems, and is directed to adhesives tolerant to plasticization by penetration enhancers used in transdermal systems. It would be clear to the skilled artisan from the '527 disclosure that crosslinking is required to impart cohesive strength. Because it is required, there needs to be some level of reactive species which it can crosslink. Every

example shows the use of acrylic acid as a functional monomer (reactive species). Use of a reactive species and crosslinker is what is supported by a fair reading of the disclosure as being the invention, what is exemplified, and what is claimed in the '527 patent.

Applicants' invention is not obvious from the '527 disclosure. Reconsideration and withdrawal of the obviousness-type double patenting rejection of claims 1-17 as obvious over the '527 patent is requested.

Claims 1, 4, 5 and 8-17 are rejected under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 5,730,999 ('999).

The '999 patent is cited by the examiner as disclosing a dermal therapeutic system which exhibits prolonged release of the drug comprising a pharmaceutical agent and an adhesive composition comprising poly(meth)acrylates in the form of at least one layer of the therapeutic system. The poly(meth)acrylates are mixtures of at least one (meth)acrylic polymer containing functional groups selected from butyl methacrylate and 2-ethyl hexyl methacrylate and at least one polymer which contain no functional groups or only insignificant amount of functional groups, which is triethylammonioethyl methacrylates that reads on non-cyclic nitrogen containing monomer. Referring to col. 4, lines 1-17, the examiner urges that the functional group containing polymers comprise 10-70%. It is then the examiner's position that the polymer containing no functional group would form 90-30 % of the composition. The examiner urges that the '999 patent discloses that the polymer composition has a Tg of -10°C to 100°C, that the disclosed transdermal system includes a backing film and a release liner, and that drugs to be delivered include fentanyl. The examiner states that the reference does not disclose crosslinking agents or reactive groups in

the composition.

Applicants submit that the claimed invention is patentable over the '999 patent.

As a preliminary matter, applicants wish to correct the examiner's reference to the teaching of the '999 patent that butyl methacrylate and 2-ethyl hexyl methacrylate are (meth)acrylic polymers containing functional groups. The 999 patent, rather, discloses butyl methacrylate and 2-ethyl hexyl methacrylate as examples of polymers that do not contain function groups. See, col. 4, lines 18-36, specifically lines 35-36).

The '999 patent discloses a dermal therapeutic system comprising a melt coated layer of a pharmaceutical agent and a mixture of poly(meth)acrylates. The mixture must comprise (1) at least one (meth)acrylate polymer containing functional groups and having a Tg of -10°C to 100°C and (2) at least one (meth)acrylate polymer that lacks functional groups or contains only insignificant amounts of functional groups. The polymer that lacks or contains an insignificant amount of functional groups has a Tg of -70°C to 80°C and is described as regulating the melt flow behavior of the poly(meth)acrylate mixture. The polymer lacking functional groups contributes to hydrogen bonding in the melt and dilutes the polymer thereby modifying viscosity. See, col. 3, lines 14-22, where the polymer component that lacks functional groups is described as regulating the melt and flow behavior of the adhesive polymer adhesive product and the polymer component that has functional groups influences drug release.

In contrast to the '999 disclosure, which requires a polymer containing functional groups, the adhesive composition of applicants' claimed invention lacks functional groups containing reactive hydrogen moieties. The (meth)acrylate polymer containing functional groups is an

indispensable component of the melt disclosed in the '999 patent. There is nothing in the '999 patent that even suggest that this component can be deleted.

The claimed invention is not anticipated by the '999 disclosure. Reconsideration and withdrawal of the rejection of claims 1, 4, 5 and 8-17 as being anticipated by the '999 patent is requested.

Claims 1-7 are rejected under 35 U.S.C. § 102 (e) as being anticipated by U.S. Patent No. 6,077,527 ('527).

The '527 patent is cited by the examiner as disclosing a pressure sensitive adhesive composition for use in transdermal drug delivery devices comprising at least 40 % by weight of alkyl acrylate including n-butyl and 2-ethylhexyl acrylate, and 10-60% by weight of substituted acrylamide, or (meth)acrylamide including t-octyl acrylamide. The Tg of the composition is said to have been calculated by the examiner to be below 10°C. The examiner further urges that the reference does not disclose any reactive groups after crosslinking.

Applicants submit that the claimed invention is patentable over the '527 patent.

Applicants again urge that from a fair reading of the '527 disclosure one skilled in the art would recognize that the described composition must contain a compound comprising a reactive hydrogen and must contain a crosslinking agent. It would be clear to the skilled artisan from the '527 disclosure that crosslinking is required to impart cohesive strength. Because it is required, there needs to be some level of reactive species which it can crosslink. Every example shows the use of acrylic acid as a functional monomer (reactive species). Use of a reactive species and crosslinker is what is supported by a fair reading of the disclosure as being the invention, what is

exemplified, and what is claimed in the '527 patent.

While the examiner urges that the '527 reference does not disclose any reactive groups after crosslinking, the skilled artisan would recognize that an excess of reactive groups over crosslinker is present since, typically, no more than 20 % of the functional groups are consumed by the crosslinker. The most functional groups are consumed where the acid is present in the least amount and the crosslinker is present in the most amount. With respect to the '527 patent, this is 2% acrylic acid and 0.46% aluminum acetyl acetonate. In this case, assuming that all the aluminum ligands react (a very conservative assumption), then only 15% of the acid functional groups are consumed by crosslinker leaving 85% unreacted. One skilled in the art would consider this to be typical. Clearly, functional groups are present in the composition of the '527 patent following crosslinking.

The '527 patent disclosure, taken as a whole, would lead away from the claimed invention. Clearly the claimed invention is not anticipated by the '527 disclosure. Reconsideration and withdrawal of the rejection of claims 1-7 as being anticipated by the '527 patent is requested.

Claims 2, 3, 6 and 7 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over U.S. Patent No. 5,730,999 ('999) in view of U.S. Patent No. 6,077,527 ('527). The examiner urges that the '999 patent discloses applicants' invention except for the specific non-cyclic nitrogen containing monomer of claims 2, 3, 6 and 7. The examiner urges that it would have been obvious to replace the non-cyclic containing monomer of '999 with the substituted acrylamide monomer of the '527 patent motivated by the '527 teaching that this combination possesses the ability to tolerate enhancers, plasticization and to resist enhancer migration.

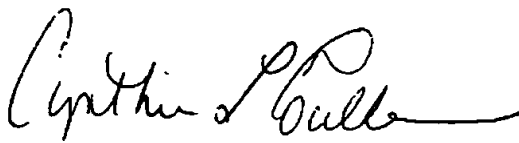
Applicants submit that the claimed invention is patentable over the '999 patent in view '527 patent.

The '999 composition requires a (meth)acrylate polymer containing functional groups as an indispensable component of the melt. In contrast, the adhesive composition of applicants' claimed invention lacks functional groups containing reactive hydrogen moieties. There is nothing in the '999 patent that even suggests that this component can be deleted. In contrast to the '999 disclosure, which requires a polymer containing functional groups, the adhesive composition of applicants' claimed invention lacks functional groups containing reactive hydrogen moieties. The (meth)acrylate polymer containing functional groups is an indispensable component of the melt disclosed in the '999 patent. There is nothing in the '999 patent that even suggests that this component can be deleted. Replacing of the nitrogen containing monomer of '999 with the nitrogen containing monomer of the '527 results in a melt having both functional and nonfunctional polymers (and also crosslinker since the '527 patent teaches that the presence of functional groups would require crosslinker). Applicants' adhesive does not have functional groups present and contains no post polymerization crosslinker.

The claimed invention is not obvious from the disclosure of the '999 patent in view of the 527 patent. Reconsideration and withdrawal of the rejection of claims 2, 3, 6 and 7 as being obvious over the '999 patent in view of the 527 patent is requested.

Early and favorable action is requested.

Respectfully submitted,



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